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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,740	10/05/2000	Sudhirdas K. Prayaga	15966-575B (Cura-75B)	8638

7590 08/18/2005

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EXAMINER	
JUEDES, AMY E	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/679,740	PRAYAGA ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

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The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/22/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S. 6-5

DETAILED ACTION

1. Misnumbered claim [32] been renumbered [33] in accordance with 37 CFR 1.126.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1-19. Claims 1-4, 38, and 41 drawn to an isolated polypeptide comprising an amino acid sequence, a mature amino acid sequence, or a variant thereof, and a pharmaceutical composition and a kit containing said polypeptides, where groups 1-19 are the polypeptides encoded by the sequences as follows:
1. SEQ ID NO 2, 47, 49 and the active peptide SEQ ID 15;
2. SEQ ID 4 and the active peptide SEQ ID 16;
3. SEQ ID NO 6 and the active peptide SEQ ID NO 17-18;
4. SEQ ID NO 8 and the fragments of SEQ ID NO 19 -20;
5. SEQ ID NO 10 and the active peptide SEQ ID NO 21;
6. SEQ ID NO 23 and the active peptide SEQ ID NO 24;
7. SEQ ID NO 26 and the active peptide SEQ ID NO 27;
8. SEQ ID NO 29 and the active peptide SEQ ID NO 30;
9. SEQ ID NO 32 and the active peptide SEQ ID NO 33;
10. SEQ ID NO 35 and the active peptide SEQ ID NO 36;
11. the variant corresponding to SEQ ID NO 37;
12. the variant corresponding to SEQ ID NO 38;
13. the variant corresponding to SEQ ID NO 39;
14. the variant corresponding to SEQ ID NO 40;
15. the variant corresponding to SEQ ID NO 41;
16. the variant corresponding to SEQ ID NO 42;
17. the variant corresponding to SEQ ID NO 43;
18. the variant corresponding to SEQ ID NO 44;
19. the variant corresponding to SEQ ID NO 45;
classified in Class 530, subclasses 300 and 350, Class 514, subclass 2, Class 435, subclass 810.

20-38. Claims 5-14, 39, and 42, drawn to an isolated nucleic acid sequence, a vector, a host cell, and a pharmaceutical composition and a kit containing said nucleic acid, where groups 20-38 are the nucleic acids encoded by the amino acid sequences as follows:
20. SEQ ID NO 2, 47, 49 and the active peptide SEQ ID 15;
21. SEQ ID 4 and the active peptide SEQ ID 16;
22. SEQ ID NO 6 and the active peptide SEQ ID NO 17-18;
23. SEQ ID NO 8 and the fragments of SEQ ID NO 19 -20;
24. SEQ ID NO 10 and the active peptide SEQ ID NO 21;
25. SEQ ID NO 23 and the active peptide SEQ ID NO 24;

26. SEQ ID NO 26 and the active peptide SEQ ID NO 27;
27. SEQ ID NO 29 and the active peptide SEQ ID NO 30;
28. SEQ ID NO 32 and the active peptide SEQ ID NO 33;
29. SEQ ID NO 35 and the active peptide SEQ ID NO 36;
30. the variant corresponding to SEQ ID NO 37;
31. the variant corresponding to SEQ ID NO 38;
32. the variant corresponding to SEQ ID NO 39;
33. the variant corresponding to SEQ ID NO 40;
34. the variant corresponding to SEQ ID NO 41;
35. the variant corresponding to SEQ ID NO 42;
36. the variant corresponding to SEQ ID NO 43;
37. the variant corresponding to SEQ ID NO 44;
38. the variant corresponding to SEQ ID NO 45;
classified in Class 536, subclass 23.1, Class 435, subclasses 320.1, 471, 810.

39-57. Claims 15-17, 40, and 43, drawn to an antibody, a pharmaceutical composition and a kit containing said antibody, where groups 39-57 are antibodies specific for the polypeptides encoded by the by the amino acid sequences as follows:
39. SEQ ID NO 2, 47, 49 and the active peptide SEQ ID 15;
40. SEQ ID 4 and the active peptide SEQ ID 16;
41. SEQ ID NO 6 and the active peptide SEQ ID NO 17-18;
42. SEQ ID NO 8 and the fragments of SEQ ID NO 19 -20;
43. SEQ ID NO 10 and the active peptide SEQ ID NO 21;
44. SEQ ID NO 23 and the active peptide SEQ ID NO 24;
45. SEQ ID NO 26 and the active peptide SEQ ID NO 27;
46. SEQ ID NO 29 and the active peptide SEQ ID NO 30;
47. SEQ ID NO 32 and the active peptide SEQ ID NO 33;
48. SEQ ID NO 35 and the active peptide SEQ ID NO 36;
49. the variant corresponding to SEQ ID NO 37;
50. the variant corresponding to SEQ ID NO 38;
51. the variant corresponding to SEQ ID NO 39;
52. the variant corresponding to SEQ ID NO 40;
53. the variant corresponding to SEQ ID NO 41;
54. the variant corresponding to SEQ ID NO 42;
55. the variant corresponding to SEQ ID NO 43;
56. the variant corresponding to SEQ ID NO 44;
57. the variant corresponding to SEQ ID NO 45;
classified in Class 530, subclass 387.1, Class 435, subclasses 130.1, 810.

57. Claims 18, 44, and 45, drawn to a method for determining the presence of a polypeptide, and the method of determining the predisposition to a disease by measuring the level of said polypeptide, classified in Class 436, subclass 537.

58. Claims 19-21, 46 and 47 drawn to a method for determining the presence of a nucleic acid, and the method of determining the predisposition to a disease by measuring the level of said nucleic acid, classified in Class 435, subclass 6.

59. Claims 22-23, drawn to a method of identifying an agent that binds to a polypeptide, classified in Class 435, subclass 7.1.

60. Claim 24, drawn to a method of identifying an agent that modulates the expression or activity of a polypeptide, classified in Class 424, subclass 278.1.

61. Claims 25, 34-37, and 49, drawn to a method for modulating the activity of a polypeptide with a compound, and a method of treating a disease with an antibody, classified in Class 424, subclass 139.1.

62. Claims 26-29, and 48, drawn to a method for treating or preventing a disease with a polypeptide, classified in Class 424, subclass 185.1.

63. Claims 30-33, drawn to a method for treating or preventing a disease with a nucleic acid, classified in Class 514, subclass 44

3. Groups 1-19, while related in that they are all polypeptides, are still patentably distinct. The polypeptides of groups 1-19 are structurally distinct, as demonstrated by their unique amino acid sequences. In addition, they are functionally distinct and are expressed in the body with unique patterns. For example, the polypeptide of group 6 is predominantly expressed in the skeletal muscle, while the polypeptide of group 7 is predominantly expressed in adipose tissue. Furthermore, the active peptide of group 8 has distinct functions in that it raises cholesterol and triglycerides, while the active peptide of group 9 lowers cholesterol and triglycerides.

4. Groups 20-38, while related in that they are all nucleic acids, are still patentably distinct. The nucleic acids of groups 20-38 all encode different proteins that are functionally and structurally distinct for the reasons indicated above.

5. Groups 39-57, while related in that they are all antibodies, are still patentably distinct. The antibodies of groups 39-57 all recognize distinct proteins. Since the proteins themselves are distinct as indicated above, the antibodies are also distinct. For example, an antibody that is administered to a subject will have a different biological effect depending on which protein it can bind.

6. Groups 1-19, 20-39, and 39-57 are different products. A polypeptide, a nucleic acid, and an antibody differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

7. Groups 1-19 and 59, 62 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of groups 1-19 can be used to generate specific antibodies.

8. Groups 20-38 and 58, 63 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid of groups 20-38 can be used to generate a protein.

9. Groups 39-57 and 57, 61 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of groups 39-57 can be used to generate anti-idiotypic antibodies

10. Groups 57-63 are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods comprising different method steps, different reagents, resulting in different endpoints. For example, the method of treating a disease requires different reagents when it is done with the nucleic acid as in group 63, the protein as in group 62, or the antibody as in group 61. Treatment of a disease with different reagents will have distinct in vivo effects, and hence will require different method steps and endpoints. Furthermore, a method of determining the presence of a polypeptide in a sample (group 57) will require different reagents (e.g. an antibody) than a method of treating a disease with a nucleic acid (group 63). In addition, different method steps and endpoints will apply for said methods.

11. Groups 1-19 and 57 are related as products and method of identifying said products. However, the method steps do not define the structure of the claimed products. Therefore, they are patentably distinct.

12. Groups 1-19 are unrelated to groups 58, 60-61, 63 because the product of groups 1-19 is not used or otherwise involved in the process of groups 58, 60-61, 63.

13. Groups 20-38 are unrelated to groups 57, 59-62 because the product of groups 20-38 is not used or otherwise involved in the process of groups 57, 59-62.

14. Groups 39-57 are unrelated to groups 58-60, 62, 63 because the product of groups 39-57 is not used or otherwise involved in the process of groups 58-60, 62, 63.

15. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by their recognized divergent subject matter. Further, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

16. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with

an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light *of In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Amy E. Juedes whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 11, 2005

8/12/05
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